

### **Remarks**

Reconsideration of this Application and entry of this Amendment are respectfully requested. Claims 1-6, 8-12, 14, 15, 18-21, 42, and 43 are pending, with claim 1 being the sole independent claim. Claims 1, 8, 9, 11 and 12 are amended. Claims 3, 6, 8, 12, 14, 15 and 21 are withdrawn pending the allowance of generic claim 1 from which they directly or indirectly depend. Claims 7, 13, 16, 17 and 22-41 are canceled without disclaimer of or prejudice to the subject matter thereof. In view of the amendments and following remarks, favorable consideration and allowance of the application are respectfully requested.

#### **Rejections Under Kusleika in View of Chouinard**

Claims 1, 2, 4, 5, and 18-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,325,815 to Kusleika et al. (“Kusleika”) in view of U.S. Pat. Appl. Pub. No. 2002/0007210 to Chouinard et al. (“Chouinard”). The Examiner states that Kusleika teaches a method of manufacturing a distal protection element that discloses each feature of independent claim 1 except for “reducing the thickness of the filaments forming the braided enclosure along at least a portion of the first end region.” Office Action p. 2. The Examiner states that Chouinard teaches a vascular device comprised of braided filaments that are reduced in diameter along at least a portion of a first end of the device noting it would be obvious to have used the reducing teaching of Chouinard in the method of Kusleika in order to provide a smaller diameter section of the filament in a tortuous portion of the stent or in a region requiring greater flexibility. Office Action p. 3. With reference to the prior amendment of claim 1, the Examiner also acknowledges that “Kusleika/Chouinard fails to explicitly teach that the reducing the thickness of the filaments takes place after the step of forming the braided enclosure.” *Id.* The Examiner then asserts that the deficiency in the combination would have been an

obvious matter of design choice to a person of ordinary skill in the art, to have reduced after braiding the enclosure because applicant has not disclosed that reducing filament thickness after braiding provides an advantage, is used for a particular purpose or solves a stated problem as opposed to reducing filament thickness prior to braiding [and the Examiner goes on to assert that] one of ordinary skill in the art would have expected applicants [sic] invention to perform equally well with either the pre-braiding reduction taught by Chouinard or the claimed post-braiding reduction because either order of steps results in the same structure.

*Id.* (emphasis added). In view of the foregoing reasoning, the Examiner states that it would have been an obvious matter of design choice to modify Kusleika/Chouinard to obtain the invention of claim 1. *Id.* at pp. 3-4.

Applicants agree with the Examiner that the combination of Kusleika and Chouinard do not teach or suggest a method of manufacturing a distal protection element that includes simultaneously reducing a thickness of all of the filaments that comprise a braided enclosure after formation of the braided enclosure as recited in the method of claim 1. Applicants respectfully disagree with the Examiner's position that this missing disclosure/teaching is a matter of design choice and particularly disagree with the Examiner's reasoning for making this obviousness rejection.

The Examiner's reasoning that it is a "matter of design choice" to have altered the order of the method steps "because *applicant has not disclosed that reducing filament thickness after braiding provides an advantage, is used for a particular purpose or solves a stated problem* as opposed to reducing filament thickness prior to braiding" seems to imply that Applicants' specification should have been written to include an advantage, purpose or problem solved by reducing the thickness of the filaments after braiding the enclosure, which now could be used as evidence that the method of claim 1 is not a matter of design choice. The notion that Applicants' specification should have been written with advantages, stated purposes and/or problems solved by the invention of claim 1 to support unknown and unforeseeable obviousness combinations is clearly contrary to the holding of In re Chu 66 F.3d 292 (Fed. Cir. 1995). In that case, Chu appealed to the Federal Circuit a decision of the BPAI that upheld an obviousness rejection of Chu's invention as "a matter of 'design choice'" because Chu's specification was silent on any purported advantage or any problem solved by the invention. In reversing the decision of the BPAI the Federal Circuit stated

[t]o require Chu to include evidence and arguments in the specification regarding whether placement of the SCR catalyst in the bag retainer was a matter of 'design choice' would be to require patent applicants to divine the rejections the PTO will proffer when patent applications are filed. ... We have found no cases supporting the position that a patent applicant's evidence and/or arguments traversing a § 103 rejection must be contained within the specification. There is no logical support for such a proposition as well, given that obviousness is determined by the totality of the record including, in some instances most significantly, the evidence and arguments proffered during the give-and-take of ex parte patent prosecution

*Id.* at 298-299. Accordingly, Applicants' specification need not have included an advantage, a stated purpose and/or a problem solved by the method of claim 1 and the lack thereof does not provide support for the Examiner's rejection of the method of claim 1 as being obvious in view of the combination of Kusleika and Chouinard as a matter of design choice.

The Examiner is also reminded that claim 1 is a method claim with a step of “reducing a thickness of all of the filaments of the braided enclosure along at least a portion of the first end region” and that Chouinard does not include any disclosure concerning how or by what process the tapered wires suggested for use in stents thereof are in fact tapered. Without any teaching or suggestion of the process Chouinard uses to obtain tapered wires, it is impossible to determine whether such a process could also be used to reduce the thickness of the filaments in the braided enclosure after formation of the braided enclosure, as required in the method of claim 1, and it is therefore speculative for the Examiner to consider the non-disclosed reducing step of Chouinard to be a matter of design choice to one of ordinary skill in the art. As such, the Examiner’s contention that claim 1 is obvious as a matter of design choice in view of the combination of Kusleika and Chouinard seems to be nothing more than impermissible hindsight reconstruction in view of Applicants’ disclosure.

For at least the foregoing reasons, the Examiner has failed to make a prima facie case of obviousness with respect to the subject matter of claim 1 such that Applicants maintain that claim 1 is patentable over and not obvious in view of the combination of Kusleika and Chouinard. Claims 2, 4, 5, and 18-20 that depend from and add further features to independent claim 1 are patentable for at least the reasons argued above with respect to the independent claim. While it is not necessary to address the Examiner’s rejection of the dependent claims at this time, Applicants reserve the right to support their patentability, when necessary. However, Applicants note that claim 18 recites that the filaments comprise “a combination of nitinol wires and drawn-filled tubing wires,” which in the Office Action dated August 25, 2008 were denoted by the Examiner as “Species M, claim 18, drawn to filaments comprising a combination of nitinol wires and drawn-filled tubing wires.” *Id.* at p. 3. In the same Office Action, the Examiner also denoted a “Species K, claim 14, drawn to filaments comprising nitinol wires” and required Applicants to elect one of “these patentably distinct species” and stated that “these species are not obvious variants of each other.” *Id.* at pp. 2-3. In the Examiner’s current rejection of claim 18 (elected species M) and the purported support thereof found in Kusleika col. 4, lines 2-16, there is disclosure of nitinol wires (provisionally withdrawn Species K, claim 14) but there is no disclosure of “a combination of nitinol wires and drawn-filled tubing wires.” In view of the Examiner’s earlier species election, Applicants contend that the purported disclosure of the subject matter of species K in Kusleika does not disclose or render obvious the patentably distinct

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species M of claim 18. Thus, the Examiner has not found a reference or combination of references that discloses or renders obvious the subject matter of claim 18 such that claim 18 is in condition for allowance.

Rejections Under Kusleika in View of Chouinard and Heilman

Claims 9-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kusleika in view of Chouinard as applied to independent claim 1 above and further in view of U.S. Patent No. 4,080,706 to Heilman et al. ("Heilman"). The Examiner relies on Heilman as teaching a tapered reduction of an element of a vascular device that is formed by electro-etching a portion of the element. *See* Office Action p. 3.

Claims 9-11 directly or indirectly depend from and add further features to independent claim 1, which is argued above as being patentable over Kusleika in view of Chouinard. Heilman does not make-up for the deficiencies of the combination of Kusleika and Chouinard. Particularly, Heilman teaches electro-etching/polishing a distal region of a core wire to remove metal therefrom, and does not teach or suggest a step of reducing a thickness of filaments that form a braided element, as recited in the method of claim 1. *See*, Heilman, col. 5, line 48-col. 6, line 19. As such the combination of Kusleika, Chouinard and/or Heilman do not render obvious claim 1. Therefore, dependent claims 9-11 are patentable over the combination of Kusleika, Chouinard and Heilman for at least the reasons argued with respect to claim 1. While it is not necessary to further address the Examiner's rejection of the dependent claims at this time, Applicants reserve the right to support their patentability, when necessary.

New Claims 42 and 43

Claims 42 and 43 directly or indirectly depend from and add further features to independent claim 1, which is argued above as being patentable over Kusleika in view of Chouinard. Therefore, dependent claims 42 and 43 are patentable over the combination of Kusleika and Chouinard for at least the reasons argued with respect to claim 1.

Conclusion

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. §1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (978) 739-3075 Eastern Time.

Respectfully submitted,

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